



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Nyle ELLIOTT

Group Art Unit: 3761

Serial No : 10/667,655

Examiner: Adam Marcetich

Filed : September 23, 2003

Confirmation No. 9116

For : COLOSTOMY ALERT DEVICE  
AND METHOD

**APPLICANT'S APPEAL BRIEF**  
**UNDER 35 U.S.C. §41.37**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**(1) REAL PARTY IN INTEREST**

The real party in interest is Oakington Corporation, the assignee of the application.

**(2) RELATED APPEALS AND INTERFERENCES**

There are no related appeals and interferences.

**(3) STATUS OF CLAIMS**

Claims 1-8, 10-12 and 21-24 are rejected and are presently the claims which are on appeal; claim 9 and 13-20 are cancelled.

Adjustment date: 03/04/2010 SMOHAMME  
08/21/2008 AWONDAF1 00000092 10667655  
01 FC:2402 -255.00 OP

**(4) STATUS OF AMENDMENTS**

An amendment after reopening of prosecution was filed on September 1, 2009. The amendment was entered and the application presently contains claims 1-8, 10-12, and 21-24.

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**(5) SUMMARY OF CLAIMED SUBJECT MATTER**

As embodied in claim 1, applicant's invention is an Aexternal@ alert device for detecting the presence of fecal matter which comprises an adhesive disposable pad having an aperture; a pH activated alarm attached to the pad; a first and second conductor wire extending from the aperture through the disposable pad to the alarm; a plug, and a third and fourth conductor on the plug, the plug being removably secured to the pad at the aperture and the third and fourth conductor each comprise a pair of spaced apart rings. The external alert device for detecting the presence of fecal matter has a disposable adhesive pad 12 having an aperture 16, is seen in figure 1. An alarm 38 is attached to the pad with a first and second conductor wire 24,26, can be seen in figure 2, extending from the aperture to the alarm. A plug 14 has a third and fourth conductor 92,94 on the plug, each being spaced apart conductive rings, as seen in figure 4, the plug being removably secured to the pad at the aperture.

Claim 2 sets forth that the alarm emits and audible alarm.

Claim 3 sets forth that the alarm emits a visible alarm.

Claim 4 sets forth that the alarm emits a tactile alarm.

Claim 5 sets forth that the alarm transmits a signal to a remote location.

Claim 6 sets forth that the plug is secured in the aperture by mating threads.

Claim 7 sets forth that the pad is a flexible, elastomeric material.

Claim 8 sets forth that the alert device further comprises an inflatable cuff encircling said plug.

Claim 10 sets forth that the alert device further includes an absorbent sleeve disposed about said plug.

Claim 11 sets forth that the plug includes a filter.

Claim 12 sets forth that the alert device further comprises an adhesive ring attached to one side of the pad.

Claim 21 further defines each of the third and fourth conductors as having a lower ring 100, 102, an upper ring 80,82 and an upwardly extending section 92,94 extending between the upper and lower rings with the upper ring extending about the outer surface and the lower ring extending about the inner surface, as seen in figure 4 and discussed in paragraph [0022].

Claim 23 recites that the first and second conductor each comprise a first section 24,26 extending from a circuit board to the aperture and a ring 20,22 extending around the aperture, as clearly seen in figure 2 and discussed in paragraph [0021].

Claim 24 addresses an external alert device for detecting the presence of fecal matter comprising: an adhesive pad having an aperture; a pH activated alarm attached to said pad; a first and second conductor extending from said aperture through said pad to said alarm; a plug, a third and fourth conductor on said plug, said plug removably secured to said pad at said aperture wherein said third and fourth conductor each comprise a pair of spaced apart conductive rings, wherein the first conductor is electrically connected to the third conductor and the second conductor is electrically connected to the fourth conductor when the plug is placed with in the aperture.

#### **(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1) Claims 1,2,4,6,7 and 21-24 stand rejected under 35 U.S.C 103(a) as being unpatentable over US 5108430(Ravo), in view of US 6171289 (Millot) in view of US Pub Number 20020019615 (Roe).

2) Claims 3 and 5 stand rejected under 35 U.S.C 103(a) as being unpatentable over US 5108430(Ravo), in view of US 6171289 (Millot) in view of US Pub Number 20020019615 (Roe) in further view of US 5266928 (Johnson).

3) Claim 8 stands rejected under 35 U.S.C 103(a) as being unpatentable over US 5108430(Ravo), in view of US 6171289 (Millot) in view of US Pub Number 20020019615 (Roe) and further in view of US 5569216 (Kim).

4) Claims 10 and 11 stand rejected under 35 U.S.C 103(a) as being unpatentable over US 5108430(Ravo), in view of US 6171289 (Millot) in view of US Pub Number 20020019615 (Roe) and further in view of US 6350255 (von Dyck).

5) Claim 12 stands rejected under 35 U.S.C 103(a) as being unpatentable over US 5108430(Ravo), in view of US 6171289 (Millot) in view of US Pub Number 20020019615 (Roe) and further in view of US 4121589 (McDonnell).

### **(7) ARGUMENT**

Rejection under 35 U.S.C 103(a) as being unpatentable over US 5108430(Ravo), in view of US 6171289 (Millot) in view of US Pub Number 20020019615 (Roe)

In response to the final Office Action and regarding Independent claim 1, applicant respectfully requests reconsideration of the claims presently on file. As the Office Action is understood, the Examiner contends that the cited art, namely Ravo, shows a pad having an aperture. The Ravo device is a hollow tubular support member (3) that is placed inside the stoma. Applicant's pad is an external pad, as the claims now clarify, that sits outside the stoma, on the patient's skin by means of an adhesive. The Ravo device is implanted surgically in the patient (column 5, lines 63-68).

The contention that the device sits at least partially external from the body is very different and not essential to the functioning of Ravo. Applicant's device, as claimed, including the pad and the plug, is a disposable external product. The implanted device of Ravo prevents it from having this crucial disposable aspect!!

Further, the Ravo circuit is activated by pressure (a predetermined pressure is attained by accumulated excremental matter). Such is critically different to the structure, as claimed and the functioning of the device.

Applicant's circuit is activated by changes in pH in the fluid inside the colon. This limitation is also set forth in independent claims 21 through 24.

The Examiner contends that Ravo has a first and second conductor extending from the aperture to the alarm. This is not accurate in that one of the electrodes that close the circuit (43) is in contact with the patient's skin. In applicant's device, all the electric circuitry goes inside the pad and none of the electric parts is in contact with the patient's skin. This limitation has also been made in claims 1 through 24.

Regarding the plug, the Ravo plug is a disk-shaped plug that is secured to the outside of the patient on the surface of the stoma. Applicant's plug is a cylindrical shaped plug that goes inside the stoma. The alarm method disclosed in the Ravo reference uses a skin-contacting electrode to generate a signal. Applicant's claimed invention does not have any skin

contacting electrodes to generate a signal. The signal is generated outside the body of the patient.

Applicant's claimed invention consists of an adhesive patch or pad that is placed outside the stoma. A cylindrical shaped plug goes through the patch and is placed inside the stoma all the way to reach the colon. The Ravo device has an inner and outer surface, but is a disk-shaped plug that sits on the outside part of the tube. The tube goes inside the stoma. This is a crucial difference in the disclosure and meaning of how the claimed invention operates.

Regarding Millot, this is a device for securing an ostomy bag about a stoma and emitting an alarm. The function of the external alarm present is very different from the Millot device. The alarm in Millot is to indicate that the pad is wet and the adhesive may not work any longer. As stated in line 10, it is a "wetness detection means" to "measuring conductivity of the adhesive composition" and sending an alarm to the patient when a certain wetness level is reached. Furthermore, the electrodes are part outside the pad and measure a chemical property happening in the skin of the patient. Applicant's connectors are inside the pad and do not measure anything in the skin of the patient. They just transmit information from the plug to the alarm. Millot merely describes the pad as an ostomy seal. Applicant's external adhesive pad is used to hold the plug. The plug acts as a barrier to the feces. Also, the use of the pad in Millot is for different purposes. While the pad in Millot is used for securing an ostomy bag, applicant's adhesive pad is used for securing the plug, which goes through the pad.

Further Roe does not fit to disclose or suggest deficiencies in the Ravo device to render Applicant's claimed device. The Examiner admits that Ravo and Millott are different structurally and are for different use!! How can adding the ph sensor of roe to this unrelated art render the claimed device obvious. Applicant has not stated that they invented the concept of a PH sensor. It is truly the unique structure, which provides a unique function that is novel and unobvious.

Claims 2-8, and 10-12 depend on claim 1 and the therefore the arguments above apply and the claims should also be allowable.

Applicant's claims clearly distinguish the present invention from the citations presented by the Examiner.

The structure, function, and how same operates are all distinctly different and as such, the application should be approved as presented.

Despite this, the Examiner finds the recited structure obvious. Under the Examiner's reasoning, an alarm between a plug and pad is obvious over the cited art regardless of the structure, location and type of the alarm, as it is all within the scope of one of ordinary skill in the art. The differences between the cited alarms and the invention do not support this conclusion.

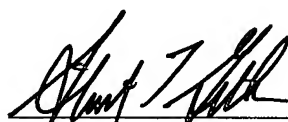
### **Conclusion**

None of the prior art of record discloses the claimed limitations regarding the claimed external alarm and its relationship with the disposable adhesive pad and plug. The Examiner recognizes this and states that the changes in geometry are within the scope of obviousness. However, under the Examiner's reasoning, the patents relied upon the Examiner would render any alarm between a pad and plug obvious, regardless of the structure of the alarm. Such a broad statement cannot be allowed to support a finding of obviousness.

It is respectfully requested that the rejections be overturned and the application allowed to issue.

Respectfully submitted,

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**CLAIMS APPENDIX**

1. An external alert device for detecting the presence of fecal matter comprising:
  - a an adhesive disposable pad having an aperture;
  - an a pH activated alarm attached to said pad;
  - a first and second conductor extending from said aperture through said disposable pad to said alarm;
  - a plug,
  - a third and fourth conductor on said plug, said plug removably secured to said pad at said aperture wherein said third and fourth conductor each comprise a pair of spaced apart conductive rings.
2. The alert device of claim 1 wherein said alarm emits an audible alarm.
3. The alert device of claim 1 wherein said alarm emits a visible alarm.
4. The alert device of claim 1 wherein said alarm emits a tactile alarm.
5. The alert device of claim 1 wherein said alarm transmits a signal to a remote location.
6. The alert device of claim 1 wherein said plug is secured in said aperture by mating threads.
7. The alert device of claim 1 wherein said pad is a flexible, elastomeric material.
8. The alert device of claim 1 further comprising an inflatable cuff encircling said plug.
9. (Cancelled)

10. The alert device of claim 1 further including an absorbent sleeve disposed about said plug.

11. The alert device of claim 1 wherein said plug includes a filter.

12. The alert device of claim 1 further comprising an adhesive ring attached to one side of the pad.

13-20. (Cancelled)

21. The alert device of claim 1, wherein the third and fourth conductors each comprise

a lower ring, an upper ring and an upwardly extending section extending between the upper and lower rings.

22. The alert device of claim 21, wherein the plug comprises a lumen having an outer surface and an inner surface,

the upper ring extending about the outer surface and the lower ring extending about the inner surface.

23. The alert device of claim 21, wherein the first and second conductor each comprise a first section extending from a circuit board to the aperture and a ring extending around the aperture.

24. An external alert device for detecting the presence of fecal matter comprising:

a an adhesive pad having an aperture;

a pH activated alarm attached to said pad;

a first and second conductor extending from said aperture through said pad to said alarm;

a plug,



a third and fourth conductor on said plug, said plug removably secured to said pad at said aperture wherein said third and fourth conductor each comprise a pair of spaced apart conductive rings, wherein the first conductor is electrically connected to the third conductor and the second conductor is electrically connected to the fourth conductor when the plug is placed within the aperture.

**EVIDENCE APPENDIX**

None

**RELATED PROCEEDINGS APPENDIX**

None